

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION  
No. 5:08-CV-00119-H

CELLECTIS S.A.,	)	
	)	
Plaintiff,	)	<b>DEFENDANT PRECISION</b>
	)	<b>BIOSCIENCES, INC.’S</b>
v.	)	<b>MEMORANDUM IN SUPPORT OF ITS</b>
	)	<b>MOTION TO STAY PROCEEDINGS</b>
	)	<b>PENDING REEXAMINATION OF</b>
PRECISION BIOSCIENCES, INC.,	)	<b>U.S. PATENT NOS. 6,610,545 AND</b>
	)	<b>7,309,645</b>
Defendant.	)	

**I. INTRODUCTION**

Defendant Precision BioSciences, Inc. (“Precision”) hereby moves to stay all proceedings in this action pending final resolution of Reexamination of U.S. Pat. No. 6,610,545 (“the ‘545 Patent”) and U.S. Pat. No. 7,309,605 (“the ‘605 Patent”) (collectively “the Patents-in-Suit”) currently pending before the United States Patent and Trademark Office (“PTO”). As described in more detail below, at Precision’s request, the PTO initiated reexamination proceedings with respect to the two Patents-in-Suit as well as two other related patents. In the last three weeks, the PTO has entered actions closing prosecution on three of the four patents under consideration. Most relevantly, the PTO has rejected all the claims at issue, including all the claims of the ‘545 Patent and the ‘605 Patent that Cellectis has asserted against Precision, on the grounds that those claims lack novelty and/or are obvious in light of several of the very same pieces of prior art and arguments that Precision relies upon in defending against the Patents-in-Suit in this litigation. In fact, following the first Office Action in the reexamination of the ‘605 Patent, the Patent Holders amended the only independent claim in that patent, and thereby narrowed all claims of that patent asserted against Precision in this case. In light of these actions by the PTO and the Patent

Holders, it is highly likely that the claims of the Patents-in-Suit currently asserted by Collectis will be cancelled or substantially amended at the conclusion of the reexamination proceedings. What is certain is that under these circumstances, proceeding with this litigation at this time is highly likely to be a waste of both the Court's and the parties' time and resources. Accordingly, a stay of the litigation pending final resolution of the reexamination of the Patents-in-Suit and any appeals is in the best interests of judicial economy.

## **II. STATEMENT OF FACTS AND STAGE OF PROCEEDINGS**

### **A. Background of the Litigation**

On March 13, 2008, Collectis filed suit against Precision, asserting infringement of the Patents-in-Suit. (*See* Complaint, Dkt. No. 1.) The Institut Pasteur (Paris, France) and the Université Pierre et Marie Curie (Paris, France) (collectively, "the Patent Holders") are the assignees of the Patents-in-Suit. On May 19, 2008, Precision filed its Answer and Counterclaims to Collectis's Complaint, including defenses and counterclaims of non-infringement, invalidity, and inequitable conduct. (*See* Answer and Counterclaims, Dkt. No. 12.)

### **B. Background and Status of the Reexamination Proceedings**

As the Court is aware, the Patents-in-Suit concern methods of using Group I intron-encoded endonucleases. Following the institution of this lawsuit by Collectis, Precision sought *inter partes* reexamination of two patents in the same family as the Patents-in-Suit, U.S. Pat. No. 7,214,536 ("the '536 Patent") and U.S. Pat. No. 6,833,252 ("the '252 Patent"), which are each also directed to methods of using Group I intron-encoded endonucleases.<sup>1</sup>

Precision's requests for reexamination of the '252 and '536 Patents were filed on March

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<sup>1</sup> Precision sought reexamination of these patents because, although Collectis had not at that time asserted them against Precision, given the similarity of those patents to the Patents-in-Suit, Precision reasonably believed they posed a threat of additional litigation.

18, 2009. On May 27, 2009, the PTO granted Precision's requests for reexamination of all claims of the '536 Patent and 18 of 19 claims of the '252 Patent, and issued first Office Actions rejecting all of the claims under reexamination.<sup>2</sup> In rejecting a number of the claims of the '536 Patent as obvious, the PTO found, for example:

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have applied the method described by Bell-Pedersen<sup>3</sup> for introducing a double stranded break and subsequent site-directed gene insertion in a bacterial cell to isolated cells from multicellular eukaryotic plants and animals, in order to transfer of [sic] genes of interest in a site directed manner into those cells. One of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success because Old<sup>4</sup> teaches the availability of a number of routine means for doing so.

(First Office Action in '536 Patent Reexamination, dated May 27, 2009, attached hereto as Exhibit 1, at 8.) Similar obviousness rejections were made over the Quirk reference<sup>5</sup> in view of the Bell-Pedersen and Old references and over the Delahodde reference<sup>6</sup> in view of Bell-Pedersen and Old. (*Id.* at 8-12.) The Bell-Pedersen, Quirk, and Delahodde references are each cited in Precision's Answer and Counterclaims as undisclosed, material prior art references that were known to the inventors or their attorneys in Precision's inequitable conduct claim. (*See*

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<sup>2</sup> On October 26, 2009, Collectis filed an amended complaint against Precision additionally alleging unfair competition in connection with Precision's issuance of press releases announcing the rejections in the first office actions in the reexaminations of the '536 and '252 patents. (*See* Amended Complaint, Dkt. No 87.) On November 13, 2009, Precision filed its answer to the amended complaint. (*See* Answer to Amended Complaint, Dkt. No. 97.) Collectis's unfair competition claim alleges that statements in Precision's press releases concerning the relationship between the rejections of the claims of the '536 and '252 patents and the asserted claims of the Patents-in-Suit were misleading. Precision maintains that the statements in its press releases were truthful and accurate. Indeed, the PTO's actions since the filing of the amended complaint, as described further herein, have unequivocally confirmed the accuracy of Precision's statements.

<sup>3</sup> Bell-Pedersen *et al.* (1990), "Intron mobility in phage T4 is dependent upon a distinctive class of endonucleases and independent of DNA sequences encoding the intron core: mechanistic and evolutionary implications," *Nucleic Acids Res.* 18:3763-70.

<sup>4</sup> Old and Primrose, *Principles of Gene Manipulation - An Introduction to Genetic Engineering*, Blackwell Scientific Publications, London (4th ed. 1989), Chapters 12 and 13.

<sup>5</sup> Quirk *et al.* (1989), "Intron Mobility in the T-Even Phages: High Frequency Inheritance of Group I Introns Promoted by Intron Open Reading Frames," *Cell* 56:455-465.

<sup>6</sup> Delahodde *et al.* (1989), "Site-Specific DNA Endonuclease and RNA Maturase Activities of Two Homologous Intron-Encoded Proteins from Yeast Mitochondria," *Cell* 56:431-441.

Precision's Answer and Counterclaims, Dkt. No. 12, at ¶¶ 21-32.) In fact, all claims of the '536 Patent were rejected as obvious in light of various combinations of these and other references and based on the same or parallel arguments to those Precision intends to rely on for its invalidity case (anticipation and obviousness) against the Patents-in-Suit. Similarly, in rejecting several of the claims of the '252 Patent as obvious, the PTO, for example, found:

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to introduce the gene of interest into a mammalian chromosome since Old *et al.* teaches method [sic] for introducing genes into mammalian organisms and Bell-Pedersen teaches method [sic] for inducing a site-directed double stranded break in the DNA of an organism by providing a cell containing the recognition site of a Group I intron encoded endonuclease (I-TevI) integrated at a location in the chromosome of the cell, and providing the Group I intron encoded endonuclease (I-TevI) to the cell. Thus a person of ordinary skill in the art would have been motivated to genetically modify a mammalian chromosome by introducing Group I intron encoded Endonucleases sequences as taught by Bell-Pedersen.

(First Office Action in '252 Patent Reexamination, dated May 27, 2009, attached hereto as Exhibit 2, at 10.) Similar obviousness rejections were made over Quirk in view of Bell-Pedersen and Old. (*Id.* at 12-15.) As with the '536 Patent, all claims of the '252 Patent under reexamination were rejected as obvious over various combinations of these and other references and based on the same or parallel arguments as those Precision intends to rely on for its invalidity case (anticipation and obviousness) against the Patents-in-Suit. (*Id.* at 7-52.)

In light of the reexamination grant with respect to these two related patents and the statements made by the PTO in its first Office Actions on these reexaminations, on July 31, 2009, Precision further sought reexamination of the two Patents-in-Suit. On September 17, 2009, the PTO granted Precision's request for reexamination of those patents and issued initial

rejections of all asserted claims of the Patents-in-Suit.<sup>7</sup> On February 1, 2010, the PTO issued an Action Closing Prosecution and rejecting all claims of the '536 and '252 Patents under reexamination. On February 18, 2010, the PTO issued an Action Closing Prosecution and rejecting all of the asserted claims of the '545 Patent, and although an Action Closing Prosecution has not yet issued in the reexamination of the '605 Patent, the positions taken and rejections by the PTO in its Action Closing Prosecution on the '545 Patent make it almost certain that a parallel action rejecting all asserted claims of the '605 Patent (as recently amended by the Patent Holders, including the newly added dependent claim 28) and closing prosecution is forthcoming.<sup>8</sup>

In rejecting the asserted claims of the Patents-in-Suit under reexamination (most recently in the Action Closing Prosecution on the '545 Patent and also in the first Office Action rejecting the asserted claims of the '605 Patent), the PTO found that the claims lack novelty and/or are obvious in light of several of the very same prior art references and arguments that Precision intends to assert against the Patents-in-Suit in this litigation. (*See* Exhibit 3, Action Closing Prosecution for '545 Patent, at 11-54; Office Action in '605 Patent Reexamination, dated Sept. 17, 2009, attached hereto as Exhibit 4, at 6-71.) In particular, most recently, the PTO stated:

Patent owner's arguments have been fully considered but are not persuasive. . . . [I]n light of the detailed explanation regarding the Quirk reference provided by the co-author Bell-Pedersen [in her declaration submitted to the PTO], the preponderance of evidence indicates that Quirk does teach providing a transgenic cell having at least one Group I [intron] encoded endonuclease recognition site inserted into the chromosome, providing an expression vector that expresses the

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<sup>7</sup> Notably, and consistent with the statements in Precision's press releases that Collectis challenged as allegedly being misleading, two references which were used to reject the independent claims of the '252 Patent and the '536 Patent were also used by the PTO to reject the independent claims of the '545 Patent and the '605 Patent.

<sup>8</sup> As discussed below, in light of the PTO's explicit findings with regard to the Sargueil (1990) reference, Collectis's amendment of the asserted independent Claim 1 of the '605 Patent is unavailing, and the asserted claims of the '605 Patent will accordingly be rejected by the PTO.

endonuclease in the cell, providing a plasmid comprising a gene of interest, transfecting the cell with the plasmid, expressing the endonuclease in the cell, and cleaving the recognition site in the chromosome to promote insertion of a gene of interest into the chromosome via homologous recombination. Thus, Quirk anticipates the '545 patent [independent] claim 7.

(Exhibit 3, Action Closing Prosecution for '545 Patent, at 13-14.) The PTO made a similar anticipation rejection based on the Bell-Pedersen reference. (*Id.* at 15-19.) In addition, as with the '536 and '252 Patents, all claims of the '545 Patent under reexamination (and all claims asserted in this lawsuit) were rejected as obvious over various combinations of Quirk, Bell-Pedersen, and other references. (*Id.* at 20-49.) Moreover, the reasoning upon which the PTO bases its anticipation and obviousness rejections is the reasoning upon which Precision relies for its invalidity case against the Patents-in-Suit in this litigation.

With respect to the claims of the '605 Patent, each independent claim under reexamination was rejected by the PTO in its first Office Action as anticipated by the Bell-Pedersen, Quirk, Delahodde, and Durrenberger<sup>9</sup> references. (*See* Exhibit 4, First Office Action in '605 Patent Reexamination, at 6-12.) Likewise, all claims of the '605 Patent under reexamination (including all claims asserted in this lawsuit) were rejected by the PTO as obvious over these and other prior art references. (*Id.* at 12-71.) Moreover, although the Patent Holders amended the asserted independent claim of the '605 Patent in response to the first Office Action to recite "chromosomal" DNA (as well as to recite "viable" cell), and an Action Closing Prosecution has not yet issued for the '605 Patent, the PTO's statements in the Action Closing Prosecution for the '545 Patent strongly indicate that this amendment will be unavailing. Specifically, in response to the Patent Holders' argument that cleavage of the chromosomal DNA

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<sup>9</sup> Durrenberger and Rochaix (1991), "Chloroplast ribosomal intron of *Chlamydomonas reinhardtii*: in vitro self-splicing, DNA endonuclease activity and *in vivo* mobility," *EMBO J* 10:3495-501.

of an organism is a novel element, the PTO stated:

Patent owner's arguments have been fully considered but are not persuasive. The examiner agrees that Sargueil '90<sup>10</sup> [cited as prior art by Precision] teaches an endonuclease-induced site-directed double-strand break in the chromosomal DNA of an organism, specifically in *E. coli*. While Sargueil '90 does teach experiments wherein cleavage of mitochondrial DNA by the endonuclease was studied, Sargueil also teaches experiments wherein the *E. coli* chromosomal DNA was cleaved by the endonuclease. . . . [The cited excerpts from Sargueil] are direct statements providing a clear teaching of an endonuclease-induced site-directed double-strand break in the chromosomal DNA of an organism.

(Exhibit 3, Action Closing Prosecution for '545 Patent, at 10-11.) This argument applies with equal force to the claims of the '605 Patent as amended.

The PTO's conclusions in rejecting **every single asserted claim** of the Patents-in-Suit on multiple grounds, and closing prosecution of the '545 Patent, therefore strongly support Precision's contention that all of the claims asserted against it in this case are invalid. Moreover, many of the key prior art references relied upon by the PTO in rejecting the claims on reexamination were clearly known to the inventors and/or their attorneys, but were never disclosed to or considered by the PTO during the original examination of the Patents-in-Suit. The PTO's reliance on these references to reject the asserted claims therefore further supports Precision's contention that these references are material and that the failure to disclose them during the original prosecutions of the Patents-in-Suit constituted inequitable conduct, rendering the Patents-in-Suit unenforceable.

### **C. Status of the Litigation**

Although the fact discovery deadline in this case was October 1, 2009, certain issues relating to fact discovery remain outstanding, and as a result some third-party discovery remains ongoing. For example, although Precision and Collectis have completed most document

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<sup>10</sup> Sargueil *et al.* (1990), "In vivo and in vitro analyses of an intron-encoded DNA endonuclease from yeast mitochondria. Recognition site by site-directed mutagenesis," *Nucleic Acids Res* 18:5659-65.

production and depositions of party-witnesses, there are a substantial number of highly relevant documents (and related deposition testimony) that are the subject of Precision's Motion to Compel, which has been briefed but not heard by Court. (*See* Dkt. Nos. 112 – 122.) In addition, Precision still seeks to depose the former head of the Institut Pasteur's Patent Department, Danielle Berneman, regarding the prosecution of the Patents-in-Suit. Although Precision requested her deposition early in fact discovery, Collectis maintained for months that she could not be made available because she had left the Institut Pasteur. Ultimately, Collectis informed Precision that Ms. Berneman would be made available for deposition on February 10<sup>th</sup>. Given that Precision maintains that Collectis has improperly withheld non-privileged documents pertaining to the prosecution of the Patents-in-Suit, however, Precision has requested that Ms. Berneman's deposition be postponed until the resolution of Precision's pending Motion to Compel. Moreover, Precision understands that Collectis is still in the process of seeking document discovery and depositions from one of Precision's customers, Pioneer Hi-Bred International, Inc. ("Pioneer"), pursuant to subpoenas issued in late September 2009.

As a result of the outstanding fact discovery, the parties have agreed to jointly seek an extension of the expert discovery deadlines in this matter. Precision takes the position that expert reports should not be exchanged until resolution of the instant motion to stay the proceedings. Collectis has agreed that the exchange of opening expert reports should be delayed at least until it is able to obtain the third-party discovery it seeks from Pioneer. In any case, the parties have not yet discussed a proposed new date for the commencement of expert discovery with opening expert reports.

Finally, although the parties have completed claim construction briefing, no date has yet been set for a *Markman* hearing in this case. Although the original case schedule called for a



trial date during Judge Howard's first civil term beginning, during, or after May 2010, no specific trial date has yet been set, and no pretrial conference has been scheduled.

### III. ARGUMENT

#### A. Background Law

Congress enacted the original reexamination statute in 1980 to "permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation." H.R. Rep. No. 96-1307 (I), 96<sup>th</sup> Cong., 2d Sess. at 3-4, *reprinted in* 1980 U.S.C. Cong. & Admin. News 6460, 6463; *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1342 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 935 (1983) ("One purpose of the reexamination procedure is to eliminate trial of [the validity] issue (when the claim is cancelled) or to facilitate trial of that issue by providing the district court with the expert view of the PTO (when a claim survives the reexamination proceeding).") The inherent authority of a district court to stay a patent litigation pending reexamination of a patent-in-suit is consistent with this policy. *See Ethicon v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) (district courts have inherent authority to stay litigation pending reexamination); *see also Landis v. North Am. Co.*, 299 U.S. 248, 254-255 (1936) (court's power to control its own docket includes authority to stay case).

District courts have recognized a "liberal policy in favor of granting motions to stay proceedings pending the outcome of USPTO reexamination or reissue proceedings." *ASCII Corp. v. STD Entm't USA, Inc.*, 844 F. Supp. 1378, 1381 (N.D. Cal. 1994); *Equipements de Transformation IMAC v. Anheuser-Busch Cos.*, 559 F. Supp. 2d 809, 816 (E.D. Mich. 2008); *Medicis Pharm. Corp. v. Upsher-Smith Labs., Inc.*, 486 F. Supp. 2d 990, 993 (D. Ariz. 2003); *see also Robert H. Harris Co. v. Metal Mfg. Co.*, 19 U.S.P.Q. 2d 1786, 1788 (E.D. Ark. 1991) ("The

legislative history surrounding the establishment of the reexamination proceeding evinces congressional approval of district courts liberally granting stays”); *Emhart Indus. v. Sankyo Seiki Mfg.*, 1987 U.S. Dist. LEXIS 15033, 3 U.S.P.Q. 2d 1889, 1890 (N.D. Ill. 1987) (“In passing the legislation establishing the reexamination proceeding, Congress stated its approval of district courts liberally granting stays within their discretion.”). District courts have acknowledged several potential benefits to staying a litigation pending resolution of reexamination proceedings:

1. All prior art presented to the Court will have been first considered by the PTO, with its particular expertise;
2. Many discovery problems relating to prior art can be alleviated by the PTO examination;
3. In those cases resulting in the effective invalidity of the patent, the suit will likely be dismissed;
4. The outcome of the reexamination proceeding may encourage a settlement without the further use of the Court;
5. The record of reexamination would likely be entered at trial, thereby reducing the complexity and length of the litigation;
6. Issues, defenses, and evidence will be more easily limited in pretrial conferences after a reexamination; and
7. The cost will likely be reduced for both the parties and the Court.

*Sorensen v. Black & Decker Corp.*, 2007 U.S. Dist. LEXIS 66712, at \*15 (S.D. Cal. Sept. 10, 2007); *Echostar Technologies Corp. v. TiVo, Inc.*, 2006 U.S. Dist. LEXIS 48431, at \*4-5 (E.D. Tex. Jul. 14, 2006); *Broadcast Innovation, L.L.C. v. Charter Communs., Inc.*, 2006 U.S. Dist. LEXIS 46623, at \*9-10 (D. Col. July 11, 2006); *Emhart Industries v. Sankyo Seikie Mfg.*, 3 U.S.P.Q. 2d 1889, 1890 (N.D. Ill. 1987).

In considering whether to stay a case pending reexamination, courts consider four primary factors: (1) whether a stay would simplify – or obviate – the issues in question and the trial of the case; (2) the stage of the litigation, including whether discovery is complete and whether the case has been set for trial; (3) whether a stay would unduly prejudice the nonmoving

party or place the nonmoving party at a tactical disadvantage; and (4) whether a stay will reduce the burden of litigation on the parties and on the court. *See Cornerstone BioPharma, Inc. v. Vision Pharma, LLC*, 2008 U.S. Dist. LEXIS 76374, at \*3 (E.D.N.C. Feb. 15, 2008); *Broadcast Innovation*, 2006 U.S. Dist. LEXIS 46623, at \*12-13; *Echostar*, 2006 U.S. Dist. LEXIS 48431, at \*4; *Tap Pharm. Prods. v. Atrix Labs., Inc.*, 2004 U.S. Dist. LEXIS 3684 (N.D. Ill. Mar. 4, 2004). “No one factor is controlling--the totality of the circumstances governs.” *Broadcast Innovation*, 2006 U.S. Dist. LEXIS 46623, at \*13. “A stay is particularly justified where the outcome of the reexamination would be likely to assist the court in determining patent validity and, if the claims were canceled in the reexamination, would eliminate the need to try the infringement issue.” *Ricoh Co. v. Aeroflex Inc.*, 2006 U.S. Dist. LEXIS 93756, at \*12 (N.D. Cal. Dec. 15, 2006).

A weighing of the factors above strongly favors a stay of this case.

**B. A Stay Will Simplify the Issues for Trial in This Case – or Obviate Them Entirely – and Also Greatly Reduce the Burden of the Litigation on the Parties and the Court.<sup>11</sup>**

As numerous courts have observed, staying an infringement action pending a PTO reexamination proceeding can simplify the issues in a case and conserve the resources of the Court as well as the parties in many ways. *See, e.g., Insituform Techs., Inc. v. Liqui-Force Servs. (USA)*, 2009 U.S. Dist. LEXIS 44116, at \*8 (E.D. Mich. May 26, 2009); *Sorensen*, 2007 U.S. Dist. LEXIS 66712, at \*15-16; *Echostar*, 2006 U.S. Dist. LEXIS 48431, at \*10-11; *Softview Computer Prods. Corp. v. Haworth, Inc.*, 2000 U.S. Dist. LEXIS 11274, at \*8-9 (S.D.N.Y. Aug. 10, 2000). As the Federal Circuit has explained, “[o]ne purpose of the reexamination procedure is to eliminate trial of [the issue of patent claim validity] (when the claim is canceled) or to

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<sup>11</sup> Precision examines these first and fourth factors together, as do a number of courts.

facilitate trial of that issue by providing the district court with the expert view of the PTO (when a claim survives the reexamination proceeding).” *Gould*, 705 F.2d at 1342.

“Courts routinely consider the expertise of the Patent Office, under which claim validity will be rigorously reevaluated [in reexamination], as an important factor in determining whether to stay its proceedings.” *Broadcast Innovation*, 2006 U.S. Dist. LEXIS 46623, at \*14; *see also Sorensen*, 2007 U.S. Dist. LEXIS 66712, at \*16-17 (“The Court believes that it will benefit from the PTO’s evaluation of how the previously unconsidered prior art references impact the claims [and that] [t]he PTO’s expert evaluation . . . is also likely to aid this Court in the preliminary process of claim construction.”); *Bausch & Lomb, Inc. v. Alcon Lab., Inc.*, 914 F. Supp. 951, 953 (W.D.N.Y. 1996) (“Because the PTO is considered to have expertise in deciding issues of patentability[,] many courts have preferred to postpone making final decisions on infringement until the PTO rules on issues before it.”). “The technical nature of the patent claims in question increases the utility of PTO expertise, which is further amplified by the need to examine prior art and publications not before the PTO during its original patent examination.” *Broadcast Innovation*, 2006 U.S. Dist. LEXIS 46623, at \*14; *see also Pegasus Development Corp. v. DirecTV, Inc.*, 2003 U.S. Dist. LEXIS 8052, at \*2 (D. Del. May 14, 2003) (deciding that by staying a highly technical case involving computer programming communication systems, “the court will gain the benefit of the PTO’s particular expertise, in that all prior art presented to the court will have been first considered by that agency”); *Brown v. Shimano American Corp.*, 1991 U.S. Dist. LEXIS 9431, at \*2 (C.D. Cal. Jan. 29, 1991) (“[R]eexamination by the PTO when issues relevant to prior art are involved is especially helpful given the PTO’s expertise.”). Where the prior art Precision has asserted against Collectis was not previously considered by the PTO and the claims are of a highly technical nature, the Court and the fact finder in this case could

benefit greatly from the PTO's evaluation and interpretations on reexamination.

At a minimum, assuming any of the presently rejected claims ultimately survive, the results of the PTO's reexaminations would simplify and narrow remaining issues through expert discovery, a *Markman* hearing, and trial. Alternatively, the PTO's efforts could eliminate the issues in this case altogether with a cancellation of the asserted claims if the present rejections are maintained. If this action proceeds and the claims of the Patents-in-Suit are subsequently cancelled, however, the time and resources expended by the Court and the parties in undertaking remaining fact discovery and expert discovery, engaging in the *Markman* hearing, and holding a trial on issues of infringement, validity, and enforceability of the Patents-in-Suit will have been wasted. Similarly, if any claims survive but are changed, the parties and Court may be forced to re-litigate each of these issues in light of the PTO's decisions.

In evaluating these risks, it is important to note that 92% of *inter partes* reexaminations result in either a cancellation of all claims or a modification of at least one claim (including 51% of cases that result in a cancellation of *all* claims). (See United States Patent and Trademark Office *Inter Partes* Reexamination Data – December 31, 2009, attached hereto as Exhibit 5.) In only 8% of all cases do the claims of a patent under *inter partes* reexamination survive unchanged. (*Id.*) A stay of the litigation eliminates the possibility of such risks, and courts regularly grant stays pending the outcome of reexamination for this very reason. See, e.g., *Insituform*, 2009 U.S. Dist. LEXIS 44116, at \*10 (“In any event, the Court is loath to hold a *Markman* hearing, rule on discovery and dispositive motions, and conduct a trial, all at great expense to the parties, when the PTO's decision could render these proceedings moot or substantially alter the claims being litigated.”); *Sorensen*, 2007 U.S. Dist. LEXIS 66712, at \*19 (“[T]he Court finds that a stay is appropriate to avoid the risk of unnecessary litigation and to

permit the clarification of issues before this Court”); *Broadcast Innovation*, 2006 U.S. Dist. LEXIS 46623, at \*23-24 (“If the PTO, utilizing its unique expertise, determines that all or some of the [asserted patent] claims are invalid, that determination will either dispose of this litigation entirely or at least aid the Court in adjudicating this case.”); *Echostar*, 2006 U.S. Dist. LEXIS 48431, at \*11 (“If the reexamination proceeding invalidates or narrows a claim or claims, the issues at trial will be simplified. . . . [T]o the extent the reexamination proceeding[s] reaffirm the claims at issue, the Court will then have the benefit of the PTO’s expert analysis of the prior art that allegedly invalidates or limits the claims.”); *Softview*, 2000 U.S. Dist. LEXIS 11274, at \*9-11.

The positions taken by the Patent Holders and the Examiners during the reexamination proceedings for the Patents-in-Suit are highly likely to eliminate outright – or at a minimum substantially narrow – the legal arguments available to the parties in this lawsuit. Moreover, the findings of the PTO will likely assist the Court in construing any surviving claims of the Patents-in-Suit and in determining whether the Patents-in-Suit are valid, enforceable, and infringed. In short, a stay of this case pending the final outcome of reexamination may eliminate the need for any further proceedings in this case at all, or, at minimum, may result in significant efficiencies and the conservation of resources for both the Court and the parties.

**C. A Stay Is Appropriate Given The Stage Of These Proceedings.**

Although much fact discovery has been conducted in this case, Precision asserts that it is still entitled to a large number of additional documents it contends have been improperly withheld by Collectis (and the Institut Pasteur) primarily based on an improper assertion of privilege, as well as additional deposition testimony on topics related to these documents. Likewise, Collectis still seeks third-party discovery from Pioneer. Expert discovery has not yet

begun in this case, and no *Markman* hearing has been scheduled. Because there has been no *Markman* hearing or ruling, summary judgment motions have not yet been filed. Finally, no specific trial date has been set.

Given the current status of the litigation, a stay would still save the Court (and the parties) the very considerable time, effort, and cost required to construe the disputed terms of claims that have already been amended by the Patent Holders and may be amended further; to consider and resolve summary judgment motions relating to infringement and invalidity based upon claims that currently stand rejected by the Patent Office as anticipated and/or as obvious; and to try to adjudicate a lawsuit on patent claims that have already been narrowed by the Patent Holders in response to rejections and, based on the reexamination record to date, are likely to be deemed invalid all together. If litigation simply proceeds, and the PTO maintains its rejections of the asserted claims of the Patent-in-Suit, these efforts will have been wasted.<sup>12</sup> See *Echostar*, U.S. Dist. LEXIS 48431, at \*4 (“Discovery is not yet completed, summary judgment motions have not been filed, and the Court has not completed its claim construction. It would be an egregious waste of both the parties’ and the Court’s resources if the *Markman* and summary judgment proceedings went forward and the claims were subsequently declared invalid or amended . . . .”) Similarly, if one or more of the asserted claims survives but in a modified form, these efforts would likely need to be duplicated.

Although some courts have pointed to the extent of fact discovery as a factor weighing against a stay, many courts have recognized that stays pending reexamination may be appropriate even when discovery is complete (or nearly complete) – or, indeed, even if a trial date is firmly

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<sup>12</sup> The Patent Holders have amended the claims of the ‘605 Patent in response to the PTO’s first office action on reexamination. Even if any of the asserted claims ultimately survived in an amended form following reexamination, if litigation proceeds, these efforts will have to be duplicated based on any surviving but amended claims.

set and imminent (which is not the case here). *See Insituform*, 2009 U.S. Dist. LEXIS 44116, at \*9 (granting stay and finding at a similar stage of litigation that “this case is one where the parties have undoubtedly spent considerable time and resources thus far, but far more time and resources are yet to be devoted to the case” (internal quotation omitted)); *Ralph Gonnocci Revocable Living Trust v. Three M Tool & Mach. Inc.*, 68 U.S.P.Q.2d 1755, 1757 (E.D. Mich. 2003) (“Courts have granted stays even where discovery has been completed, and even when a trial date has been scheduled or is forthcoming.”); *Perricone v. Unimed Nutritional Services, Inc.*, 2002 U.S. Dist. LEXIS 17613, at \*3 (D. Conn. 2002) (noting that courts “have granted stays pending re-examination proceedings notwithstanding the well-developed posture of the litigation”). Moreover, “courts considering this factor do not stop at discovery and trial settings, but rather, routinely inquire as to the occurrence [of] summary judgment arguments, rulings on summary judgment, and the status of the final pretrial order, among other elements.” *Broadcast Innovation*, 2006 U.S. Dist. LEXIS 46623, at \*14; *see also Gioello Enters. v. Mattel, Inc.*, 2001 U.S. Dist. LEXIS 26158, at \*3-5 (D. Del. Jan. 29, 2001) (noting trial was set, but expressing concern for pending summary judgment motions); *Softview*, 2000 U.S. Dist. LEXIS 11274, at \*3 (same concern as summary judgment motions and unfinished final pretrial order).

Many courts have recognized that sunk costs and effort in discovery are neither dispositive of whether a stay should be granted nor necessarily wasted by virtue of a stay if the patents ultimately survive reexamination. As noted recently in *Insituform*, “discovery costs incurred to date ‘will not be recouped by denying a stay and proceeding to a trial’ . . . Nor will the completed discovery prove useless if the patents are held valid and the stay lifted.” 2009 U.S. Dist. LEXIS 44116, at \*9 (quoting *Middleton Inc. v. Minn. Mining & Mfg. Co.*, 2004 U.S. Dist. LEXIS 16812, at \*21 (S.D. Iowa Aug. 24, 2004)); *Softview*, 2000 U.S. Dist. LEXIS 11274,



at \*8-9 (noting that the costs of the litigation to the patent holder to date will not be affected by the grant or denial of a stay and that if the litigation proceeds and the PTO later finds some or all of the claims invalid, the Court will have wasted time and the parties will have spent additional funds addressing invalid claims). Moreover, “the parties’ costs would only be enhanced if the Court were to proceed to trial and later find that the patents had been modified or invalidated.”

*Id.*

In short, the fact that substantial fact discovery has already occurred in this case does not weigh against the grant of a stay. As stated by the court in *Broadcast Innovation*,

For every court that yields to completed discovery and a looming trial date, another court finds these dates outweighed by other factors—be it the complexity of the suit, the value of PTO expertise, simplification of the issues, lack of hardship to the nonmovant, or the overall burden of duplicitous litigation on the parties and on the court. Put simply, [the stage of the litigation proceedings] doesn’t always tell the tale.

2006 U.S. Dist. LEXIS 46623, at \*27-28; *see also Gould*, 705 F.2d at 1342 (granting motion to stay five years into litigation and twenty days before scheduled trial date); *Motson v. Franklin Covey Co.*, 2005 U.S. Dist. LEXIS 34067, at \*4-5 (D.N.J. Dec. 16, 2005) (granting stay despite discovery being complete and summary judgment decided); *Middleton*, 2004 U.S. Dist. LEXIS 16812, at \*3-4 (granting motion to stay proceedings eight years after start of litigation and less than two months before trial); *Softview*, 2000 U.S. Dist. LEXIS 11274, at \*9 (holding, in granting stay, that “although there has been a great deal of activity in this litigation to date, much remains to be done before the case is ready for trial”).

In consideration of both the substantial work that remains to be done in connection with fact and expert discovery, the *Markman* hearing that is yet to be scheduled, and motions for summary judgment that will follow, and in the absence of any firm schedule for trial, a stay of this litigation, especially in light of the PTO’s actions on reexamination, is appropriate.

**D. Collectis Will Not Be Prejudiced By a Stay.**

A stay pending reexamination will not unduly prejudice Collectis or place Collectis at a tactical disadvantage. As an initial matter, Collectis, too, will benefit from the conservation of resources that a stay will afford. Furthermore, courts have held explicitly that the “delay inherent to the reexamination process does not constitute, by itself, undue prejudice.” *KLA-Tencor Corp. v. Nanometrics, Inc.*, 2006 U.S. Dist. LEXIS 15754, at \*7 (N.D. Cal. Mar. 16, 2006); *see also Insituform Techs., Inc. v. Liqui-Force Servs. (USA)*, 2009 U.S. Dist. LEXIS 44116, at \*6 (E.D. Mich. May 26, 2009). In the event that the rejections of the claims of the Patents-in-Suit are withdrawn or reversed on appeal, Collectis will still have an adequate remedy at law – even after the Patents-in-Suit expire – of potentially obtaining money damages from Precision, which would be fully capable of compensating Collectis. In fact, with respect to the ‘605 Patent, since Collectis amended the asserted claims in response to the PTO’s rejections in its first Office Action on reexamination, Collectis would only be entitled to money damages for infringement of substantially modified surviving claims (if any) from the date of issuance of a certificate of reexamination. Collectis can hardly claim prejudice for a delay that would prevent collection of damages for infringement of versions of claims of the ‘605 Patent that the Patent Holders voluntarily modified in an attempt to escape rejection on reexamination.

With respect to any injunctive relief that is sought, Collectis did not seek a temporary restraining order or a preliminary injunction, and courts have found that failure to seek such remedies is evidence that a stay would not be unduly prejudicial. *See Insituform*, 2009 U.S. Dist. LEXIS 44116, at \*7; *Equipements de Transformation*, 559 F. Supp. 2d at 816; *Magna Donnelly Corp. v. Pilkington N. Am., Inc.*, 2007 U.S. Dist. LEXIS 17536, at \*14 (E.D. Mich. Mar. 12, 2007); *VData, LLC v. Aetna, Inc.*, 2006 U.S. Dist. LEXIS 84876, at \*5 (D. Minn. Nov. 21, 2006)

(adopting findings of magistrate to grant stay).

In contrast to instances in which a defendant seeks a stay merely to gain a tactical advantage of delay over the plaintiff by forestalling a likely adverse judgment, Precision seeks no such advantage here. Indeed, if the fact finder here were to share the PTO's apparent views regarding the validity of the Patents-in-Suit, Precision would actually be forestalling a favorable judgment. Given the PTO's actions in rejecting the asserted claims of the Patents-in-Suit in reexamination, however, Precision, a small start-up company, wishes to save (both parties) enormous expenses in legal fees, expert witness fees, vendor fees, and trial costs for a litigation that will very likely be rendered completely moot after the reexaminations are complete and appealed at the Board of Patent Appeals and Interferences ("BPAI").<sup>13</sup>

While Collectis will not be unduly prejudiced by a stay, Precision, on the other hand, may suffer severe prejudice (even apart from the expense of litigation) if a stay is not granted. The Federal Circuit has confirmed that the PTO is not bound in its reexamination by the determinations of any district court. *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1296-98 (Fed. Cir. 2007). In recognition of this, a number of courts have reasoned:

Not only could the Court and the PTO reach conflicting determinations, but one possible scenario could result in irreparable harm to [Defendant]: if this Court finds that the [patent] is not invalid and that [Defendant] has infringed it, and orders [Defendant] to pay damages to [Plaintiff] for such infringement, then [Defendant] would have no ability to recover those damages if at a later date the PTO determined that the [] patent is invalid.

*Bausch & Lomb*, 914 F. Supp. at 952; *see also Sorensen*, 2007 U.S. Dist. LEXIS 66712, at \*15.

The court in *Sorensen* found "such a possibility to be, at a minimum, a highly undesirable outcome." *Sorensen*, 2007 U.S. Dist. LEXIS 66712, at \*15. Indeed, the likelihood of such a

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<sup>13</sup> A patent is not revised by any amendment or cancellation of a claim made during a reexamination proceeding until a reexamination certificate is issued following expiration of the appeals period or resolution of appeal at the BPAI. *See* 35 U.S.C. § 307.

possibility, which would harm Precision irreparably, weighs heavily in favor of granting a stay.

#### **IV. CONCLUSION**

For all of the foregoing reasons, Precision respectfully requests that the Court stay all further proceedings in this case, pending the final outcome of the reexamination of the Patents-in-Suit.

This the 23<sup>rd</sup> day of February, 2010.

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## CERTIFICATE OF SERVICE

I hereby certify that, on the 23<sup>rd</sup> day of February, 2010, I electronically filed the foregoing Defendant Precision BioSciences, Inc.'s Memorandum in Support of Motion to Stay Proceedings Pending Reexamination of U.S. Patent Nos. 6,610,545 and 7,309,645 with the Clerk of Court using the CM/ECF system, which will send notification to the attorneys of record for Cellectis S.A. as follows:

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